K080125

Wako Wako Diagnostics

JUL 18 2008

SECTION 9

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
The assigned 510(k) number is K080125.

807.92 (a)(1): Name: **Wako Diagnostics**
Address: 665 Clyde Avenue, Suite B
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Phone: (650) 210-9153
FAX: (650) 210-9170
Contact: **Peter Panfili, Ph.D.**

807.92 (a)(2): Device name- trade name and common name, and classification

Trade Name:

APOLOWAKO Lipid Panel*, composed of;
APOLOWAKO T-CHO
APOLOWAKO HDL-C
APOLOWAKO TG
APOLOWAKO Analyzer and accessories
* APOLOWAKO Lipid Panel is a generic name for the above three reagents for lipids determination in whole

Common Name:

Test system for individual reporting of:
- total cholesterol
- HDL cholesterol
- triglycerides
- LDL cholesterol (by Friedewald calculation)
- Discrete photometric chemistry analyzer for clinical use

Wako Wako Diagnostics

Classification:

Total cholesterol: §21.862.1175
HDL cholesterol: §21.862.1475
Triglycerides: §21.862.1705
LDL cholesterol: §21.862.1475 (by calculation)
Discrete photometric chemistry analyzer for clinical use: §21.862.2160

807.92 (a)(3): Identification of the legally marketed predicate device

CHOLESTECH LDX, Cholestech Corporation, Hayward, CA cleared under K954778 and K946067 for lipids.

807.92 (a)(4): Device Description

The APOLOWAKO analyzer is a fully-integrated POC test system that can perform up to six analytical tests per individual sample. The analyzer automatically separates plasma from whole blood for testing. Once the plasma has been separated, it is transferred to a cell on a measurement disk where the chemical reactions take place. The analyzer uses liquid reagents which are packaged into kits. Each kit contains 2 reagent units. Each unit is composed of two enzyme color reagents and a lyophilized calibrator. All of the reagents have a reagent information tag applied to the back of each bottle which controls the reagent parameters and conditions such as, calibration, reagent quantity, shelf-life, and lot number. The instrument contains an automated liquid dispenser, temperature controlled reagent carrousel, analysis compartment, and sample holder. The instrument is designed to automatically and constantly monitor the reagents, dispensing system, measurement disk, and measurement process to ensure that no erroneous results are shown. The APOLOWAKO's lipid panel will include, total cholesterol, HDL cholesterol, LDL cholesterol (by calculation), and triglycerides in tubed venous whole blood. The test system is designed for professional use and consists of a small table top instrument (31 cm wide x 47.5 cm high x 56 cm deep, weight: 25 kg).

807.92 (a)(5): Intended Use

The APOLOWAKO Lipid Panel is for the quantitative determination of total cholesterol, HDL cholesterol and triglycerides in whole blood and also calculates and gives results for LDL cholesterol and the T-CHO/HDL-C ratio.

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Wako Diagnostics

807.92 (a)(6): Technological Similarities and Differences to the Predicate

Similarities / Differences between the APOLOWAKO Lipid Panel and Established Predicate Device (Cholestech LDX)

CHARACTERISTIC	APOLOWAKO Analyzer	Cholestech LDX System
Intended Use	The APOLOWAKO Lipid Panel is used for the *in vitro* quantitative determination of total cholesterol, HDL cholesterol, LDL cholesterol (by calculation), triglycerides in whole blood and the T-CHO/HDL-C ratio.	The Cholestech LDX System is used for the quantitative determination of total cholesterol, HDL (high-density lipoprotein) cholesterol and triglycerides glucose in whole blood. A TC/HDL (total cholesterol/HDL cholesterol ratio and estimated values for LDL (low density lipoprotein) and non-HDL cholesterol are calculated by the Cholestech LDX.
Indications for Use	The measurement of total cholesterol, HDL cholesterol, LDL cholesterol, and triglycerides when used in conjunction with other biochemical markers and coronary risk factors, is useful in the prediction of CHD/CVD risk and the assessment of CHD/CVD severity.	Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders such as diabetes mellitus, atherosclerosis, and various liver and renal diseases.
Sample	Whole blood	Whole blood
Sample Preparation	Venous whole blood sample	Finger stick or venous whole blood sample
Calibration	Calibration is required at the time the reagent is opened and lasts for 28 days or until expiration date.	No calibration is performed by the user.
Methodology	Colorimetric, enzyme-based	Colorimetric
Reagent Format	Liquid	Dry
Testing Environment	Professional use, point-of-care	Professional use, point-of-care

Reportable range	**T-CHO: 25-330** mg/dL **HDL-C: 8.0-100** mg/dL **TG: 30-625** mg/dL **LDL-C** by calculation	**T-CHO: 100 to 500** mg/dL **HDL-C: 15-100** mg/dL **TG: 45-650** mg/dL **LDL-C** by calculation
Precision	**T-CHO:** Total imprecision less than 2.0% CV across a range of **133** mg/dL to **788** mg/dL (mean values) **HDL-C:** Total imprecision less than 2.0% CV across a range of **38.8** mg/dL to **100.3** mg/dL (mean values) **TG:** Total imprecision less than 2.0% across a range of **90** mg/dL to **1178** mg/dL (mean values)	**T-CHO:** Total imprecision less than 4.0% across a range of **161** mg/dL to **244** mg/dL (mean values) **HDL-C:** Total imprecision less than 6.5% CV across a range of **29** mg/dL to **46** mg/dL (mean values) **TG:** Total imprecision less than 3.2% across a range of **121** mg/dL to **276** mg/dL (mean values)
Linearity	Assay linear throughout reportable range	Assay linear throughout reportable range
Interfering Substances	No interference from high levels of bilirubin (conjugated and unconjugated), hemoglobin, EDTA-2Na, heparin sodium and ascorbic acid. No interference from triglycerides on T-CHO and HDL-C measurements.	There are 23 substances including hemoglobin, bilirubin and uric acid that did not interfere with the assay. Free glycerol does affect Cholestech TG test but it does not affect APOLOWAKO TG.

807.92 (b)(1): Brief Description of Non-clinical Data

Evaluations were performed for within-day imprecision, between-day imprecision, linearity, and interfering substances. Those resulting data are summarized below.

Triglyceride

Within-day imprecision, when evaluated at three levels of triglyceride (low- 45 mg/dL, intermediate- 139 mg/dL, and high- 1209 mg/dL), ranged from 0.5 % CV to 2.9 % CV. Between-day imprecision, when evaluated in duplicate over 10 days, ranged 0.9 % CV to 1.8 % CV.

Results from linearity studies demonstrated that the triglyceride is linear throughout the reportable range.

Results from an interference testing showed triglyceride assay is not affected by high levels of hemoglobin, bilirubin (conjugated or unconjugated) or free glycerol.

Total Cholesterol
Within-day imprecision, when evaluated at three levels of total cholesterol (low- 122 mg/dL, intermediate- 187 mg/dL, and high- 764 mg/dL), ranged from 0.5 % CV to 1.2 % CV. Between-day imprecision, when evaluated in duplicate over 10 days, ranged 0.6 % CV to 1.7 % CV.

Results from linearity studies demonstrated that the total cholesterol is linear throughout the reportable range.

Results from an interference testing showed that the total cholesterol is not affected by high levels of hemoglobin, bilirubin (conjugated or unconjugated), triglycerides, ascorbic acid, EDAT-2Na, or heparin sodium.

HDL-C
Within-day imprecision, when evaluated at three levels of HDL-C (low- 30.8 mg/dL, intermediate- 51.1 mg/dL, and high- 95.2 mg/dL), ranged from 0.5 % CV to 1.6 % CV. Between assay imprecision, when evaluated in duplicate over 10 days, ranged 0.5 % CV to 1.6 % CV.

Results from linearity studies demonstrated that the HDL-C assay is linear throughout the reportable range.

Results from an interference testing showed that the HDL-C is not affected by high levels of hemoglobin, bilirubin (conjugated or unconjugated), triglycerides, ascorbic acid, EDAT-2Na, or heparin sodium.

807.92 (b)(2): Brief Description of Clinical Data

The method comparison study shows substantial equivalence to FDA cleared comparison methods for total cholesterol, triglycerides and HDL-cholesterol. For each analyte, 388 (384 for HDL-cholesterol; 4 samples out of the detectable range) broadly distributed samples showed statistically significant correlation with the reference method with slopes approaching 1.0 and y-intercepts approaching zero. APOLOWAKO results were collected under rigorous conditions sufficient to meet the requirements for CLIA Waiver. The results show correlation coefficients of 0.945 or better for each assay.

807.92 (b)(3): Conclusions from Non-clinical and Clinical Testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JUL 18 2008

Wako Chemicals USA, Inc.
c/o Peter Panfili, Ph.D.
665 Clyde Avenue, Suite B
Mountain View, CA 94043

Re: k080125
Trade/Device Name: APOLOWAKO T-CHO, APOLOWAKO HDL-C, APOLOWAKO TG and APOLOWAKO Analyzer and accessories
Regulation Number: 21 CFR 862.1175
Regulation Name: Cholesterol (total) test system
Regulatory Class: Class I
Product Code: CGO, CDT, LBS and JJE
Dated: June 24, 2008
Received: June 30, 2008

Dear Dr. Panfili:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number ~~(800) 638-2041 or (240) 276-3150 or at its Internet address at~~ http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k080125

Device Name:
APOLOWAKO T-CHO
APOLOWAKO HDL-C
APOLOWAKO TG
APOLOWAKO Analyzer and accessories

Intended Use
The APOLOWAKO T-CHO is for the quantitative determination on the APOLOWAKO analyzer of total cholesterol in whole blood. The APOLOWAKO HDL-C is for the quantitative determination on the APOLOWAKO analyzer of HDL cholesterol in whole blood. The APOLOWAKO TG is for the quantitative determination on the APOLOWAKO analyzer of triglycerides in whole blood. In conjunction with the above values, the APOLOWAKO analyzer also calculates LDL cholesterol for triglyceride values up to 400 mg/dL and T-CHO/HDL-C ratio.

APOLOWAKO Analyzer is a discrete photometric chemistry analyzer for clinical use in both central laboratories and in point of care sites. The device is intended to duplicate manual analytical procedures by automatically performing various steps such as pipetting, mixing and measuring color intensity. This device is intended for use in conjunction with certain materials to measure a variety of analytes of clinical interest in whole blood samples.

Indications for Use
The measurements of total cholesterol, HDL cholesterol, triglycerides, and LDL cholesterol (by calculation for triglyceride values up to 400 mg/dL) when used in conjunction with other biochemical markers and coronary risk factors, is useful in the prediction of CHD/CVD risk and the assessment of CHD/CVD severity.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K080125